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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/713,336	11/13/2003	Paul Ashton	CDSI-P01-030	9868

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EXAMINER	
SHEIKH, HUMERA N	

ART UNIT	PAPER NUMBER
1618	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/713,336	ASHTON ET AL.	
	Examiner	Art Unit	
	Humera N. Sheikh	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 June 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 12-37* is/are pending in the application.

4a) Of the above claim(s) *18-20* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,12-17 and 21-37* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Application

Receipt of the Response after Non-Final Office Action, the Amendment, Applicant's Arguments/Remarks, the request for extension of time (3 months-granted) and the Terminal Disclaimer, all filed 06/18/08 is acknowledged.

Applicant has overcome the following rejection(s): **(1)** The nonstatutory obviousness-type double patenting rejection of claims 1, 12-17 and 21-37 over claims 1-17 of U.S. Patent No. 6,375,972 has been withdrawn by virtue of the submission of a Terminal Disclaimer; **(2)** The 35 U.S.C. §102(b) rejection of claims 1, 30-33 and 36 over Smith *et al*. (USPN 5,378,475) has been withdrawn; **(3)** The 35 U.S.C. §103(a) rejection of claims 1, 12-17 and 21-37 over Groenewegen (USPN 5,989,581), Zaffaroni (USPN 3,948,254), Zaffaroni (USPN 3,854,480) and Visser (USPN 5,935,597) has been withdrawn; **(4)** The 35 U.S.C. §103(a) rejection of claims 1, 12-17 and 21-37 over Zaffaroni ('254) in view of Zaffaroni ('480) and Visser ('597) has been withdrawn; by virtue of the amendment to the claims.

Claims 1 and 12-37 are pending in this action. Claims 1, 26-29 and 32 have been amended. Claims 2-11 and 38 have been cancelled. Claims 18-20 remain withdrawn. Claims 1, 12-17 and 21-37 remain rejected.

* * * * *

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 12-17 and 21-37 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 43, 46, 49, 50, 55, 58, 61, 63-67 and 70-74 of copending Application No. 10/096,877 ('877 application). Although the conflicting claims are not identical, they are not patentably distinct from each other because the '877 application also claims a sustained release drug

delivery system comprising a drug reservoir comprising a therapeutically effective amount of an agent; an inner tube having first and second ends and covering at least a portion of said drug reservoir, said inner tube being dimensionally stable and capable of supporting its own weight; and an outer layer covering at least a portion of said drug reservoir and/or inner tube, wherein upon implantation, agent is released through at least one of the open ends.

The only differences observed between the '877 application and the instant claims are that claim 1 of '877 does not recite an impermeable member located at the inner tube, first end and does not recite a permeable member positioned at said inner tube first/second ends. However, note that claim 46 recites the limitation that the sustained release drug delivery system further comprises "an impermeable member positioned at said inner tube, first end". Also note claims 49 & 50, which recite the limitation that the sustained release drug delivery system further comprises "a permeable member positioned at said inner tube first/second ends". Instant claim 1 recites a specific class of therapeutic agent – "antiviral", whereas claim 1 of '877 is generic and recites "an agent". However, note that claim 70 of '877 claims that the agent is an "anti-viral agent". Asides from these distinctions, the inventions of the instant application and the '877 application are essentially similar.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

* * * * *

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1, 12-17 and 21-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Smith *et al.* (U.S. Pat. No. 5,378,475) in view of Visser (U.S. Pat. No. 5,935,597).

Smith *et al.* ('475) teach sustained release drug delivery devices and methods for treating a mammalian organism to obtain a desired local or systemic physiological or pharmacological effect. The device includes an inner core or reservoir comprising the effective agent; a first coating layer, which is essentially impermeable to the passage of the effective agent; and a second coating layer, which is permeable to the passage of the effective agent. the first coating layer covers at least a portion of the inner core; however, at least a portion of the inner core is not coated with the first coating layer. The second coating layer essentially completely covers the first coating layer and the uncoated portion of the inner core (see Abstract); (col. 1, lines 5-20).

Smith et al. teach that the first layer must be selected to be impermeable to the passage of the agent from the inner core out to adjacent portions of the second coating layer. The purpose is to block the passage of the agent to those portions and thus control the release of the agent out of the drug delivery device (col. 7, lines 10-33).

Natural or synthetic materials that can be used in the device include cross-linked polyvinyl alcohol, plasticized nylon, silicone rubbers and the like (col. 6, lines 41-66). See also column 8, lines 49-68).

Regarding Applicant's limitation of "an inner tube that is dimensionally stable and capable of supporting its own weight", it is the position of the Examiner that the coating(s) taught by Smith are sufficient to meet this limitation. Smith teach a coating layer that may be applied directly in the form of a *sheet or membrane* to the outer surface of the agent (col. 9, lines 1-34). This "sheet or membrane" can be interpreted as a solid layer that would be sufficient to support its own weight and would also be dimensionally stable. The inner tube claimed by Applicant has not been defined (*i.e.*, by reciting specific thickness parameters) so as to distinguish over the coatings of Smith. The coatings of Smith could also be considered as rigid structures, capable of supporting their own weight.

Smith does not teach the antiviral – nevirapine.

Visser ('597) teach drug delivery devices and methods for treating viral and microbial infections comprising active agents effective for the treatment of such viral or microbial conditions (see Abstract); (col. 1, lines 13-24). Visser teach that active agents effective for the treatment of infection, such as HIV include nevirapine (col. 7, line 65 – col. 8, line 15).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate the antiviral agent - nevirapine, as taught by Visser within the devices of Smith. One would be motivated to do so with a reasonable expectation of success because Visser teach drug delivery devices that utilize antiviral agents, particularly, nevirapine and teach that nevirapine is an effective drug used for the beneficial treatment of viral infections and conditions. The expected result would be an

enhanced drug delivery system that efficiently combats viral diseases for the user in need thereof.

With regards to the instant amounts claimed, such as the instant amounts of active agent, the Examiner points out that generally, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). Furthermore, amounts and/or ranges are routine-optimized variables capable of being determined by one of ordinary skill in the art through manipulative experimentation to obtain the best possible results, as these are variable parameters attainable within the art.

Response to Arguments

Applicant's arguments filed 06/18/08 have been fully considered and were found partially persuasive.

- **Double Patenting Rejection:**

Applicant argued, "Claims 1, 12-19, and 21-37 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-17 of 6,375,972. Applicants enclose herewith a terminal disclaimer thereby rendering this rejection moot. Applicants respectfully request reconsideration and withdrawal of this rejection."

These arguments were persuasive. The nonstatutory obviousness-type double patenting rejection of claims 1, 12-19 and 21-37 over U.S. Patent No. 6,375,972 has been withdrawn, by virtue of the submission of a Terminal Disclaimer (filed 06/18/08).

- **Double Patenting Rejection:**

Applicant argued, "Claims 1, 12-19, and 21-37 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 43, 46, 49, 50, 55, 58, 61, 63-67 and 70-74 of copending application 10/096,877. Applicants will address this rejection when it is no longer provisional."

The double patenting rejection has been maintained. The instant claims have not been amended so as to overcome the double patenting rejection, nor has a terminal disclaimer been filed over the copending application 10/096,877.

- **Rejection under 35 U.S.C. §102(b) over Smith (USPN 5,378,475):**

Applicant argued, "Smith teaches a sustained release drug delivery device which includes an inner core or reservoir comprising an effective agent, a first coating, and a second coating. Applicants assert that there is no teaching or suggestion of a device comprising an inner tube that is *dimensionally stable and capable of supporting its own weight.* In contrast, Smith describes a device that merely has an impermeable and a permeable *coating.* Applicants assert that a coating is not capable of supporting its own weight, whereas the inner tube of the pending claims is capable of supporting its own weight (see page 15, lines 12-14 of the specification).

These arguments were found persuasive. The 35 U.S.C. §102(b) rejection of claims 1, 30-33 and 36 over Smith ('475) has been withdrawn, by virtue of the amendment to the claims.

- **35 U.S.C. 103(a) rejection of claims 1, 12-17 and 21-37 over Groenewegen (US 5,989,581) in view of Zaffaroni (US 3,948,254) and Zaffaroni (US 3,854,480) and Visser (US 5,935,597):**

Applicant argued, "Groenewegen describes a device comprising a thermoplastic polymer core and an "ethylene-vinylacetate copolymer skin" (column 4, lines 16-17). Applicants assert that there is no teaching or suggestion of a device comprising an inner tube that is *capable of supporting its own weight and is dimensionally stable.* In contrast, Groenewegen describes a device that merely has a copolymer skin on the polymer core. Applicants assert that a *skin,* like a coating, is not capable of

supporting its own weight, whereas the inner tube of the pending claims is capable of supporting its own weight (see page 15, lines 12-14 of the specification).

Zaffaroni ('254) describes a device comprising a wall surrounding a reservoir containing a drug, wherein the wall is formed at least in part of a microporous material. Applicants assert that there is no suggestion or motivation to modify Zaffaroni such that the device comprises an inner tube that is *capable of supporting its own weight and is dimensionally stable* at all, much less an inner tube that also has first and second open ends.

Zaffaroni ('480) teaches a drug delivery device comprising an inner matrix and an outer polymeric membrane, wherein suitable drugs include antiviral drugs. Conceptually, this device is similar to Groenewegen, in that it has a drug-containing core surrounded by a skin or membrane. Applicants assert that there is no suggestion or motivation to modify Zaffaroni such that the device comprises an inner tube that is *capable of supporting its own weight and is dimensionally stable,* particularly since this element is entirely absent from both references.

Visser teaches a drug delivery device, such as a transdermal patch, for delivery of an antiviral medication. Applicants assert that Visser provides no suggestion or motivation to modify Zaffaroni such that the device comprises an inner tube that is *capable of supporting its own weight and is dimensionally stable.* "

Applicant's arguments have been considered and were found persuasive. The 35 U.S.C. §103(a) rejection has been withdrawn, by virtue of the amendment to the claims.

- **35 U.S.C. 103(a) rejection of claims 1, 12-17 and 21-37 over Zaffaroni (US 3,948,254) in view of Zaffaroni (US 3,854,480) and Visser (US 5,935,597):**

Applicant argued, "For the reasons discussed above, the device of the pending claims is patentable over Zaffaroni ('480) and Zaffaroni ('254) in view of Visser."

Applicant's arguments have been considered and were found persuasive. The 35 U.S.C. §103(a) rejection has been withdrawn, by virtue of the amendment to the claims.

- **35 U.S.C. 103(a) rejection of claims 1, 12-17 and 21-37 over Smith (US 5,378,475) in view of Visser (US 5,935,597):**

Applicant argued, "The Examiner states that it would have been obvious to one of ordinary skill in the art to incorporate the antiviral agent of Visser within the device of Smith. Applicants assert that, for the reasons discussed above, the device of the pending claim is patentable over Smith; Visser offers nothing to teach or suggest the inner tube as recited in the pending claims."

Applicant's arguments have been fully considered but were not deemed persuasive. Regarding Applicant's limitation of "an inner tube that is dimensionally stable and capable of supporting its own weight", it is the position of the Examiner that the coating(s) taught by Smith are sufficient to meet this limitation. Smith teach a coating layer that may be applied directly in the form of a *sheet or membrane* to the outer surface of the agent (col. 9, lines 1-34). This "sheet or membrane" can be interpreted as a solid layer that would be sufficient to support its own weight and would also be dimensionally stable. The inner tube claimed by Applicant has not been defined (*i.e.*, by reciting specific thickness parameters) so as to distinguish over the coatings of Smith. The coatings of Smith could also be considered as rigid structures, capable of supporting their own weight. The secondary reference of Visser amply fills the deficiency of the primary reference in their teaching of drug delivery devices and methods for treating viral and microbial infections comprising active agents such as nevirapine.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

--No claims are allowed at this time.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Humera N. Sheikh whose telephone number is (571) 272-0604. The examiner can normally be reached on Monday-Friday during regular business hours.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley, can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status

information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Humera N. Sheikh/

Primary Examiner, Art Unit 1618

hns

September 03, 2008